

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
For Emit® 2000 Thyroxine Assay**

K000600

I. Manufacturer and Contact Information:

Manufacturer: Syva Company - Dade Behring Inc.
20400 Mariani Avenue.
Cupertino, CA 95014

Contact Information: Paul Rogers
Syva Company
3403 Yerba Buena Road
San Jose, CA 95161-9013
Tel: 408-239-2000

II. Device Classification Name:

The Clinical Chemistry and Clinical Toxicology Devices Panel have classified "Thyroxine Test System" as Class II.

III. Intended Use:

Emit® 2000 Thyroxine Assay is a homogeneous enzyme immunoassay. The assay is intended for use in the quantitative analysis of thyroxine in human serum or plasma.

IV. Device Description and Characteristics:

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

The Emit® 2000 Thyroxine Assay is a homogenous enzyme assay intended for use in quantitative analysis of thyroxine in human serum or plasma. The Emit® 2000 Thyroxine Assay and calibrators has been found to be equivalent to the predicate device: Emit® Thyroxine Assay (K880620) with regard to intended use, assay sample, and overall performance characteristics.

Comparative Analysis: The Emit® 2000 Thyroxine Assay and calibrators showed excellent correlation to the predicate method. The comparative analysis to the predicate method resulted in a correlation of 1.00 with a slope value of 0.99.

Precision: A Precision study was performed and the Emit® 2000 Thyroxine Assay demonstrated acceptable within-run precision with coefficients of variation (%CV) ranging from 0.84% to 2.44% and acceptable total precision with coefficients of variation (%CV) ranging from 1.13% to 2.91%.

Sensitivity: The sensitivity level of the Emit® 2000 Thyroxine Assay is 0.65 µg/dL thyroxine. This level represents the lowest measurable concentration of thyroxine that can be distinguished from 0 µg/dL with a confidence of 95%.

Endogenous Interference: Endogenous interference due to bilirubin, hemoglobin, and triglycerides, in the Emit® 2000 Thyroxine assay, are 104, 99, and 104% respectively.

High Sample Dilution: The recovery of the mean calculated high samples, diluted with Emit® 2000 Negative Calibrator, and tested on the Emit® 2000 Thyroxine Assay is 103% when compared to the Emit® Thyroxine predicate.

Anticoagulants: The performance of the anticoagulants potassium EDTA and sodium heparin as compared to serum was tested on the Emit® 2000 Thyroxine Assay. Average recovery, compared to the serum control was 96% for the EDTA and 101% for the sodium heparin.

Calibration Stability: The Emit® 2000 Thyroxine Assay has a calibration stability of at least 14 days.

V. Substantial Equivalence:

In conclusion, Syva Company – Dade Behring Inc. considers the Emit® 2000 Thyroxine Assay and Emit® 2000 Thyroxine Calibrators to be substantially equivalent to the Emit® Thyroxine Assay (K880620) and Emit® 2000 Thyroxine Calibrators with regard to intended use, assay sample, and overall performance characteristics.



MAR 27 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Paul L. Rogers Jr.
Senior Manager, Regulatory Affairs
Syva Company - Dade Behring Inc.
P.O. Box 49013
3403 Yerba Buena Road
San Jose, California 95135

Re: K000600
Trade Name: Emit® 2000 Thyroxine Assay
Emit® 2000 Thyroxine Calibrator
Regulatory Class: II
Product Code: KLI, JIS
Dated: February 22, 2000
Received: February 23, 2000

Dear Mr. Rogers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

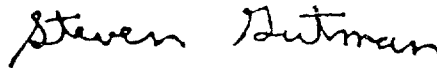
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large, stylized 'S' and 'G'.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure


510(k) Number (If known):

K000600

Device Name: Emit® 2000 Thyroxine Assay
Emit® 2000 Thyroxine Calibrators

Indications for Use:

The Emit® 2000 Thyroxine Assay is a homogenous enzyme immunoassay intended for use in the quantitative analysis of thyroxine in human serum or plasma as an aid to the diagnosis and management of thyroid disease. The Emit® 2000 Thyroxine Assay is designed for use on a variety of chemistry analyzers.


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000600

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)